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10/771,388	02/05/2004	Horst Georg Zerbe	2004_0189	3058

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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
01/21/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/771,388	ZERBE ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2010*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-23,26,27,29,31,33-60 and 62-66* is/are pending in the application.

4a) Of the above claim(s) *41-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-23,26,27,29,31,33-40,52-60 and 62-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed November 10, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

1) Claims 10-18, 20, 21, 23, 26, 27, 57, 58 and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554, already of record) in view of Pullen et al. (US 5,328,682).

Majeti discloses films comprising one or more layers for the delivery of nicotine transmucosally. The compositions comprise polymers such as polyvinyl alcohol, hydroxypropyl cellulose, polyethylene oxide homopolymers, polyvinyl pyrrolidone (PVP) and mixtures thereof. The polymers may comprise 40% to 90% of the composition (col. 4, line 55 to col. 5, line 5). Plasticizers are included such as polyethylene glycol and sorbitol (col. 5, lines 45-53) and may comprise from 2% to 10%. The adhesive layer'

thickness ranges from 0.1 mm to 7 mm. The concentration of nicotine varies from 1mg to 100mg (col. 4, lines 9-11) and comprises 1% and 2% of the Examples, encompassing claims 26 and 27. Aromatic oils are included in the compositions and include menthol (col. 6, lines 6-21), encompassing claim 21. Other ingredients include chlorhexidine, dispersants, surfactants, humectants, pigments and colorings, encompassing claim 12. Actives also include caffeine.

The reference differs from the instant claims insofar as it does not disclose the type of surfactants or that a mixture of surfactants may be used.

Pullen et al. disclose mouthwashes and is used as a general teaching to disclose surfactants suitable for oral compositions. Surfactants are used to aid in wetting and to solubilize flavoring oils when present. The surfactants include anionic, amphoteric, nonionic and mixtures thereof. These surfactants include block copolymers such as ethylene oxide and propylene oxide copolymers, e.g. Poloxamer 184 (encompassing a alpha hydroxyl-omega-hydroxypoly(oxyethylene)-poly(oxypropylene)poly(oxyethylene) block copolymer as recited in the instant claims), ethoxylated hydrogenated castor oil (encompassing a polyoxyethylene castor oil derivative as recited in the instant claims), and ethoxylated sorbitan esters (encompassing a polyoxyethylene sorbitan fatty acid ester). Preferred compositions comprise 0.2 to 2.5% by weight of surfactant (col. 2, lines 51-68).

The reference differs from the instant claims insofar as it does not disclose a dry film.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used a combination of an alpha hydroxyl-omega-hydroxypoly(oxyethylene)-poly(oxypropylene)poly(oxyethylene) block copolymer and a polyoxyethylene castor oil derivative as the surfactants in the compositions of Majeti motivated by the desire to use surfactants that are suitable for oral compositions and may be used in mixtures as disclosed by Pullen et al. Also see MPEP 2144.07.

In regards to the film exhibiting instant wettability followed by rapid dissolution, the films of the reference are made of substantially the same water soluble polymers, such as PVP and hydroxyalkyl cellulose, in substantially the same amounts as the instant claims and therefore should have substantially the same properties because the polymers control the wettability and dissolution of the film. Pullen et al. disclose surfactants are added to aid in wetting the compositions, thus, the incorporation of surfactants would reasonably be expected to add to the wettability of the compositions. Although this is disclosed for a mouthwash, it is reasonable to conclude that the surfactants can add to the wettability of the compositions of Majeti because the compositions are first made by mixing them in a solution (col. 5, lines 40-44 discloses solubilizing the components in solvents). Furthermore the polymer and mixture of polymers used affect the amount and the rate of delivery of the active. The solubility of the layer controls the release of the active (col. 4, lines 37-40). Thus, it would take no more than routine optimization and the relative skill of one of ordinary skill in the art to

determine the proportions of polymers and surfactant to arrive at a film with the desired rate of water hydration and dissolution. See MPEP 2144.05 II.

2) Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554, already of record) in view of Pullen et al. (US 5,328,682) as applied to claims 10-18, 20, 21, 23, 26, 27, 57, 58 and 62-65 above, in further view of Pader (US 4,082,841).

Majeti in view of Pullen et al. is discussed above and differs from the instant claim insofar as they do not disclose the compositions further comprise polyoxyethylene alkyl ether as a surfactant used in combination with hydroxyl-omega-hydroxypoly(oxyethylene)-poly(oxypropylene)poly(oxyethylene) block copolymer, a polyoxyethylene castor oil derivative and polyoxyethylene sorbitan fatty acid ester.

Pader disclose oral compositions and is used as a general teaching to disclose nonionic surfactants suitable for oral care. The surfactants include polyoxyethylene fatty acid ethers and sorbitan fatty acid ester and their polyoxyethylene derivatives, encompassing claim 19. The surfactants are used to solubilize flavoring oils in mouthwashes (col. 5, lines 3-10).

The reference differs from the instant claims insofar as it does not disclose a dry film.

Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows

logically from their having been individually taught in the prior art. See MPEP 2144.06. It would have been obvious to one of ordinary skill in the art to have incorporated polyoxyethylene fatty acid ethers and polyoxyethylene sorbitan fatty acid ester in the compositions comprising mixtures of surfactants as disclosed in the combined teachings of Majeti and Pullen et al. motivated by the desire to use nonionic surfactants suitable for oral compositions and to make a third surfactant system that is able to perform the same function of solubilizing flavor oils. See MPEP 2144.06.

3) Claims 22, 29, 31, 33-40, 53-56 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554, already of record) in view of Pullen et al. (US 5,328,682) as applied to claims 10-18, 20, 21, 23, 26, 27, 57, 58 and 62-65, in further view of Acharya (US 5,686,094, already of record).

Majeti and Pullen et al. are discussed above and differ from the instant claims insofar as they do not disclose that the polymer used in the disclosed composition is hydroxypropyl methyl cellulose or that tartaric acid is a flavor enhancer as recited in claim 22.

Acharya teaches polymeric delivery systems which can be used in the oral cavity. It is disclosed using cellulose polymers control the release rate of the actives from the film matrix. Cellulose polymers include methylcellulose, hydroxypropyl methyl cellulose, hydroxypropyl cellulose, hydroxymethyl cellulose or hydroxyethyl cellulose, cellulose, gum xanthan and mixtures thereof (col. 5, lines 44-60). Other conventional ingredients, which may optionally be present, include preservatives, stabilizers,

plasticizers, co-solvents, anti-adherents or silica flow conditioners as well as FD&C colors (col. 6, lines 48-61). Other ingredients that can be present in the compositions include breath fresheners and flavors, e.g., spearmint oil, peppermint oil, menthol and tartaric acid (col. 9, lines 10-15), which is a flavor enhancer.

The reference differs from the instant claims insofar as it does not teach using two surfactants in the compositions and the dimensions of the films.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have incorporated tartaric acid as a flavor enhancer and hydroxypropyl methyl cellulose in combination with PVP as a mixture of essential components in the compositions of the combined teachings of Majeti and Pullen et al. motivated by the desire to use the components for their known function as water soluble or water dispersible polymers and flavor enhancing agents. It would have been obvious for one of ordinary skill in the art to have combined hydroxypropyl methyl cellulose and PVP in the films of the combined teachings to form a third polymer system used for the very same purpose. See MPEP 2144.06.

In regard to claim 66, the surfactants are used as wetting agents and as solubilizers for flavoring oils. The surfactants affect the wettability of the compositions and the solubilization of the components therein. It would have taken no more than the relative skill of one of ordinary skill in the art to have adjusted the amount of each

surfactant to a ratio of 1:5 to 1:3 in the compositions in order to achieve the desired wettability and solubilization of the flavoring agents, as supported by MPEP 2144.05.

4) Claims 52, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554, already of record) in view of Pullen et al. (US 5,328,682) and Acharya (US 5,686,094, already of record) as applied above in further view of Dam (USP 5,733,574, already of record) and Stanley (USP 5,783,207, already of record).

Majeti, Pullen et al. and Acharya are discussed above and differ from the instant claims insofar as they do not disclose the compositions comprise caramel or nicotine salicylate.

Dam discloses compositions for treating nicotine addiction. The compositions are formulated into gels and comprise nicotine or their salts. The compositions comprise coloring agents such as caramel, sweeteners, flavoring and stabilizing agents such as tartaric acid. The reference differs from the instant claims insofar as it does not disclose the compositions are a monolayer films or the compositions comprise water-soluble polymers.

Stanley et al. teach dosage forms comprising nicotine and its salts. Nicotine is released from a dosage form and absorbed through the intra-oral mucosal surfaces as the nicotine-containing matrix releases nicotine within the user's mouth. Nicotine is available in either the free base or salt form. Nicotine base is readily absorbed through mucosal membranes but is highly volatile. Nicotine salts, on the

other hand, are not readily absorbable through mucosal membranes but are much more stable. Pharmaceutically acceptable nicotine salts include, but are not limited to nicotine hydrochloride and nicotine salicylate. In an alkaline environment, i.e., pH above about 7, and in the presence of an aqueous medium, such as saliva within the oral cavity, nicotine salts react to form nicotine base. In addition to nicotine in a releasable form, which is readily absorbed transmucosally; the nicotine-containing compositions in accord with the present invention may contain other ingredients such as flavorings, sweeteners, flavor enhancers, lubricants, binders and fillers. The reference differs from the instant claims insofar as it does not teach the matrices as being able to rapidly disintegrate or soften immediately.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have incorporated nicotine salts and caramel in the compositions of the combined teachings of Majeti, Pullen et al. and Acharya motivated by the desire to use a coloring agent disclosed by the art as suitable for nicotine comprising compositions.

It would have been obvious to one of ordinary skill in the art to have used nicotine salicylate in the compositions of the combined teachings of Majeti, Pullen et al. and Acharya motivated by the desire to produce a dosage form wherein the active ingredient was stable as disclosed by the Stanley.

Claims 10-23, 26, 27, 29, 31, 33-40, 52-60 and 62-66 are rejected

Claims 41-51 are withdrawn

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612